Exhibit 146

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.

Civil Action No. 07-10248-PBS

Exhibit to the July 24, 2009, Declaration of James J. Fauci In Support of Plaintiff's Motion for Partial Summary Judgment and In Opposition to the Roxane Defendants' Motion For Partial Summary Judgment

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287:1
                   UNITED STATES DISTRICT COURT
               FOR THE DISTRICT OF MASSACHUSETTS
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   3
       IN RE: PHARMACEUTICAL ) MDL NO. 1456
   4
       INDUSTRY AVERAGE WHOLESALE ) CIVIL ACTION
   5
   6
       PRICE LITIGATION ) 01-CV-12257-PBS
       THIS DOCUMENT RELATES TO
   7
                                 )
   8
       U.S. ex rel. Ven-a-Care of ) Judge Patti B. Saris
       the Florida Keys, Inc.
   9
  10
                                 ) Chief Magistrate
          v.
  11
       Abbott Laboratories, Inc., ) Judge Marianne B.
  12
       No. 06-CV-11337-PBS ) Bowler
  13
          (cross captions appear on following pages)
  15
               Videotaped deposition of SUE GASTON
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                           Volume II
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  20
                              Washington, D.C.
  21
                              Wednesday, March 19, 2008
  22
                              9:00 a.m.
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288:1
               UNITED STATES DISTRICT COURT
       FOR THE DISTRICT OF MASSACHUSETTS
   2
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                             ) 01-CV-12257-PBS
   6
      PRICE LITIGATION
   7
                             ) Judge Patti B. Saris
     THIS DOCUMENT RELATES TO
   8
                             ) Chief Magistrate
      ALL CASES IN MDL NO. 1456 ) Judge Marianne B.
   9
  10
      ---- Bowler
  11
  12
        IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
  13
             THIRD JUDICIAL DISTRICT AT ANCHORAGE
  15
      STATE OF ALASKA,
  16
               Plaintiff,
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                             )
  18
         vs.
                             ) Case No.
  19
      ALPHARMA BRANDED PRODUCTS ) 3AN-06-12026 CI
  20 DIVISION, INC., et al.
                             )
  21
              Defendants.
  22 - - - - - - - - - - - -
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- 322:1 what type of drugs and the criteria basically was
 - 2 drugs that were considered outpatient drugs,
 - 3 generally dispensed at the pharmacy level.
 - 4 Q. And we talked about this last time.
 - 5 But you were aware that you specifically took
 - 6 steps to exclude infusion and injectable drugs
 - 7 from the mechanism by which the FULs were
 - 8 calculated, correct?
 - 9 MS. MARTINEZ: Objection, form.
 - 10 A. Correct.
 - 11 Q. Do you recall any discussions about
 - 12 perhaps changing the HCFA policy or criteria not
 - 13 to establish FULs for injectable and infusion
 - 14 drugs at any point in time?
 - 15 A. I know that the conversation was
 - 16 probably discussed. I don't know when. But no
 - 17 steps were taken to do that.
 - 18 Q. Can you tell me why not steps were
 - 19 taken to do that?
 - 20 A. It's my understanding that the criteria
 - 21 we were using is to set federal upper limit
 - 22 prices on drugs that were most commonly used.

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- 323:1 When we stepped into the arena of injectable
 - 2 drugs or other drugs that weren't most commonly
 - 3 used, I think it was a little more difficult to
 - 4 capture those drugs for various reasons. So
 - 5 that's why we stuck with the basic criteria that
 - 6 we used.
 - 7 Q. But you believe that there were
 - 8 discussions about possibly moving injectable
 - 9 infusion drugs into the FUL program; is that fair
 - 10 to say?
 - 11 A. I wouldn't say that specifically.
 - 12 There could have been conversations. I wouldn't
 - 13 say that the conversations went as far as to say
 - 14 let's move them into the FUL arena. But the
 - 15 conversations were there. And I can only answer
 - 16 that generally, because I only remember short
 - 17 conversations maybe discussing the issue.
 - 18 Q. If there has been testimony from Mr.
 - 19 Bentley that he -- his best recollection is that
 - 20 he advised you of the large differences between
 - 21 acquisition cost and AWPs for certain injectable
 - 22 infusion drugs at least as early as 1990, could

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- 456:1 Q. And Ms. Bergin's note indicates that in
 - 2 this instance CMS did not set a FUL because the
 - 3 FUL price would have been equal to Major's AWP;
 - 4 is that correct?
 - 5 A. Correct.
 - 6 Q. Are you familiar with making that kind
 - 7 of a decision not to set a FUL when it was equal
 - 8 to an AWP?
 - 9 A. Yes.
 - 10 Q. Why would CMS decline to set a FUL when
 - 11 the FUL was equal to an AWP?
 - 12 A. Because states have other methodologies
 - 13 they can use for reimbursement. And their
 - 14 regular reimbursement methodology would be a
 - 15 percentage off of AWP. That would be a
 - 16 reasonable reimbursement rate for other drugs.
 - $\,$ 17 $\,$ So the purpose of setting the FUL price is to try
 - 18 to set reasonable reimbursement. And that would
 - 19 kind of counter what the states were doing with
 - 20 their other reimbursement methodology.
 - 21 Q. I see. So just like we talked about
 - there morning, one of the objectives of the FUL

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- 457:1 program is cost savings?
 - 2 A. Correct.
 - 3 Q. And so if you set a FUL that was equal
 - 4 to an AWP it wouldn't really result in any cost
 - 5 savings to the state?
 - 6 A. Correct.
 - 7 Q. And so in this case, if I understand
 - 8 what's going on here with cefadroxil in 2001,
 - 9 basing a FUL on the lowest published price seemed
 - 10 to result in a FUL that was too low, right?
 - 11 A. It appeared that way because of the
 - 12 compendia information that we have.
 - Q. And setting a FUL -- not using that
 - 14 lowest published price but moving up to the next
 - 15 seemed to result in a FUL that was too high?
 - 16 A. Correct.
 - $\ensuremath{\text{Q}}.$ And so CMS declined to set a FUL given
 - 18 the published prices that were out there?
 - 19 A. Correct.
 - Q. Let me just digress here for a second.
 - 21 What role if any did AWP play in setting FULs?
 - 22 A. Generally, it did not.

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- 528:1 Q. Would you have had access to that AMP
 - 2 information?
 - 3 A. Yes.
 - 4 Q. Did you ever use that AMP information
 - 5 in setting FULs?
 - 6 A. No.
 - 7 Q. Did you ever use that AMP information
 - 8 $\,$ in terms of evaluating and the approval of state
 - 9 Medicaid plans?
 - 10 A. State Medicaid plans are for the
 - 11 states. So we really wouldn't use AMPs.
 - 12 Q. Well, as I understand it, one of your
 - 13 responsibilities -- one of your other
 - 14 responsibilities was approving state Medicaid
 - 15 plans, right?
 - 16 A. Correct.
 - Q. And to get approval, one of the things
 - 18 a state had to demonstrate was the reasonableness
 - of its reimbursement rates?
 - 20 A. Correct. Their methodology.
 - 21 Q. Their methodology.
 - 22 A. Correct.

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- 529:1 Q. And I guess what I'm wondering is in
 - 2 examining the reasonableness of the methodology,
 - 3 the reasonableness of the reimbursement rates the
 - 4 state was proposing to pay, if you ever looked at
 - 5 AMP information.
 - 6 A. No.
 - 7 Q. Switching back to putting your FUL hat
 - 8 back on, what if anything did CMS do to monitor
 - 9 when drugs were coming off patents and therefore
 - 10 going generic?
 - 11 A. Well, when I was doing the FUL program
 - 12 basically I just waited to get notification if
 - 13 somebody would let me know. I really didn't do
 - 14 anything proactively, because I just didn't have
 - 15 the capability of doing it or the time.
 - 16 Q. Is it different today? Do you know?
 - 17 A. I don't know.
 - 18 Q. And who typically will let you know
 - 19 that something came off patent and therefore went
 - 20 generic?
 - 21 A. Industry folks. I can't say
 - 22 specifically. But sometimes pharmacies might

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